

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA**

SHIRE DEVELOPMENT LLC,)	
SHIRE PHARMACEUTICAL)	
DEVELOPMENT INC.,)	
COSMO TECHNOLOGIES LIMITED,)	
and)	C.A. No. 1:12-cv-00904-AT
GIULIANI INTERNATIONAL)	
LIMITED,)	
)	
Plaintiffs,)	
)	
v.)	
)	
OSMOTICA KERESKEDELMI ÉS)	
SZOLGÁLTATÓ KFT, OSMOTICA)	
PHARMACEUTICAL CORP., and)	
OSMOTICA PHARMACEUTICAL)	
ARGENTINA S.A.,)	
)	
Defendants.)	

AMENDED JOINT PRELIMINARY REPORT AND DISCOVERY PLAN

Pursuant to Local Rule 16.2 of the Civil Local Rules of Practice for the United States District Court for the Northern District of Georgia, Plaintiffs Shire Development LLC, Shire Pharmaceutical Development Inc., Cosmo Technologies Limited, and Giuliani International Limited (collectively, “Plaintiffs”) and defendants Osmotica Kereskedelmi és Szolgáltató Kft (“Osmotica Kft”), Osmotica Pharmaceutical Corp. (“Osmotica Pharmaceutical”), and Osmotica Pharmaceutical Argentina S.A. (“Osmotica Argentina”) (collectively, “Defendants”) hereby submit

this Amended Joint Preliminary Report and Discovery Plan.

1. Description of Case

(a) Describe briefly the nature of this action.

This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code involving United States Patent No. 6,773,720 (“the ’720 patent”).

(b) Summarize, in the space provided below, the facts of this case. The summary should not be argumentative nor recite evidence.

Plaintiff Shire Development LLC is the owner of New Drug Application (“NDA”) No. 22-000, approved by the U.S. Food and Drug Administration (“FDA”) for the manufacture and sale of mesalamine delayed release tablets commercialized under the trade name Lialda[®]. FDA’s publication titled “Approved Drug Products with Therapeutic Equivalence Evaluations” (commonly known as the “*Orange Book*”) lists the ’720 patent as covering Lialda[®]. The ’720 patent, titled “Mesalazine Controlled Release Oral Pharmaceutical Composition,” issued on August 10, 2004 to Cosmo S.p.A, on assignment from inventors Roberto Villa, Massimo Pedrani, Mauro Ajani, and Lorenzo Fossati.

Osmotica Pharmaceutical has filed, on behalf of Osmotica Kft, Abbreviated New Drug Application (“ANDA”) No. 203043 (“the Osmotica ANDA”), which seeks FDA approval to market mesalamine delayed release tablets containing 1.2 g

of mesalamine as the active ingredient (“the Osmotica ANDA Product”). ANDA No. 203043 includes certification that the ’720 patent is invalid or will not be infringed by the manufacture, use, or sale of the Osmotica ANDA Product. Submission of such certification constitutes a technical act of infringement under 35 U.S.C. § 271(e)(2)(A) that creates subject matter jurisdiction for a patent infringement action.

Plaintiffs allege that the commercial manufacture, use, sale, offer for sale and/or importation into the United States of the Osmotica ANDA Product will infringe one or more claims of the ’720 patent under 35 U.S.C. § 271. Defendants deny that such conduct will infringe the ’720 patent and contend that the ’720 patent is invalid under one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and 112.

(c) The legal issues to be tried are as follows:

- (1) Whether Plaintiffs have proven by a preponderance of evidence that the commercial manufacture, use, or sale of the Osmotica ANDA Product would infringe the ’720 patent, either literally or under the doctrine of equivalents;

- (2) Whether Plaintiffs have proven by a preponderance of evidence that Osmotica Kft will contribute to and/or actively induce infringement of the '720 patent;
- (3) Whether Defendants have proven by clear and convincing evidence that the '720 patent is invalid under 35 U.S.C. §§ 101, 102, 103 or 112;
- (4) Whether this case is exceptional under 35 U.S.C. § 285, thereby entitling Plaintiffs or Defendants to attorneys' fees;
- (5) Whether Plaintiffs are entitled to injunctive relief prohibiting Defendants from infringing the '720 patent.

(d) The cases listed below (include both style and action number) are:

(1) Pending Related Cases:

Shire Development LLC, Shire Pharmaceutical Development Inc., Cosmo Technologies Limited, and Giuliani International Limited v. Cadila Healthcare Limited (d/b/a Zydus Cadila) and Zydus Pharmaceuticals (USA) Inc., C.A. No. 10-581-KAJ (D. Del.).

Shire Development LLC, Shire Pharmaceutical Development Inc., Cosmo Technologies Limited, and Giuliani International Limited v. Watson Pharmaceuticals, Inc. and Watson Laboratories, Inc. – Florida, Case 0:12-cv-60862 (S.D. Fla.)

(2) Previously Adjudicated Related Cases:

None.

2. This case is complex because it possesses one or more of the features listed below (please check):

- (1) Unusually large number of parties
- (2) Unusually large number of claims or defenses
- ✓ (3) Factual issues are exceptionally complex
- ✓ (4) Greater than normal volume of evidence
- ✓ (5) Extended discovery period is needed
- (6) Problems locating or preserving evidence
- (7) Pending parallel investigations or action by government
- ✓ (8) Multiple use of experts
- ✓ (9) Need for discovery outside United States boundaries
- ✓ (10) Existence of highly technical issues and proof

Defendants disagree that (a) the factual issues presented in this case are “exceptionally complex,” (b) that greater than normal volume of evidence is likely to be an issue in this case, or (c) that there exists highly technical issues and proof.

3. Counsel:

The following individually-named attorneys are hereby designated as lead counsel for the parties:

Plaintiffs: Edgar H. Haug
Frommer Lawrence & Haug LLP
745 Fifth Avenue
New York, New York 10151

Defendants: Robert F. Green
Leydig, Voit & Mayer, Ltd.
180 N. Stetson Ave, Suite 4900
Chicago, Illinois 60601

4. Jurisdiction:

Is there any question regarding this Court's jurisdiction?

_____ Yes ✓ No

If "yes," please attach a statement, not to exceed one (1) page, explaining the jurisdictional objection. When there are multiple claims, identify and discuss separately the claim(s) on which the objection is based. Each objection should be supported by authority.

Defendants Osmotica Kft and Osmotica Argentina deny that this Court has personal jurisdiction over them; however, for purposes of this action only, Osmotica Kft and Osmotica Argentina will not contest personal jurisdiction.

5. Parties to This Action:

(a) The following persons are necessary parties who have not been joined:

None are alleged at this time.

(b) The following persons are improperly joined as parties:

None. However, as noted above, Defendants Osmotica Kft and Osmotica Argentina deny that this Court has personal jurisdiction over them; however, for purposes of this action only, Osmotica Kft and Osmotica Argentina will not contest personal jurisdiction.

(c) The names of the following parties are either inaccurately stated or necessary portions of their names are omitted:

None.

(d) The parties shall have a continuing duty to inform the Court of any contentions regarding unnamed parties necessary to this action or any contentions regarding misjoinder of parties or errors in the statement of a party's name.

6. Amendments to the Pleadings:

Amended and supplemental pleadings must be filed in accordance with the time limitations and other provisions of Fed. R. Civ. P. 15. Further instructions regarding amendments are contained in LR 15.

(e) List separately any amendments to the pleadings that the parties anticipate will be necessary:

The parties do not anticipate the need to amend their pleadings at this time, but reserve their right to amend consistent with the Federal Rules of Civil Procedure and the Civil Local Rules of Practice for the United States District Court for the Northern District of Georgia.

(f) Amendments to the pleadings submitted LATER THAN THIRTY DAYS after the Joint Preliminary Report and Discovery Plan is filed, or should have been filed, will not be accepted for filing, unless otherwise permitted by law.

7. Filing Times for Motions:

All motions should be filed as soon as possible. The local rules set specific filing limits for some motions. These times are restated below.

All other motions must be filed WITHIN THIRTY DAYS after the beginning of discovery, unless the filing party has obtained prior permission of the court to file later. Local Rule 7.1A(2).

(g) *Motions to Compel*: before the close of discovery or within the extension period allowed in some instances. Local Rule 37.1.

(h) *Summary Judgment Motions*: within thirty days after the close of discovery, unless otherwise permitted by court order. Local Rule 56.1.

(i) *Other Limited Motions*: Refer to Local Rules 7.2A, 7.2B, and 7.2E, respectively, regarding filing limitations for motions pending on removal, emergency motions, and motions for reconsideration.

(j) *Motions Objecting to Expert Testimony*: Daubert motions with regard to expert testimony no later than the date that the proposed pretrial order is submitted. Refer to Local Rule 7.2F.

8. Initial Disclosures:

The parties are required to serve initial disclosures in accordance with Fed. R. Civ. P. 26. If any party objects that initial disclosures are not appropriate, state the party and basis for the party's objection. NOTE: Your initial disclosures should include electronically stored information. Refer to Fed. R. Civ. P. 26(a)(1)(B).

9. Request for Scheduling Conference:

Does any party request a scheduling conference with the Court? If so, Please state the issues which could be addressed and the position of each party.

The parties have agreed upon certain modifications to the case schedule contemplated by the Local Patent Rules of the Northern District of Georgia, as discussed in further detail in Section 10.

10. Discovery Period:

The discovery period commences thirty days after the appearance of the first defendant by answer to the complaint. As stated in LR 26.2A, responses to initiated discovery must be completed before expiration of the assigned discovery period.

Cases in this Court are assigned to one of the following three discovery tracks: (a) zero month discovery period, (b) four months discovery period, and (c) eight month discovery period. A chart showing the assignment of cases to a discovery track by filing category is contained in Appendix F. The track to which a particular case is assigned is also stamped on the complaint and service copies of the complaint at the time of filing.

Please state below the subjects on which discovery may be needed:

The parties currently anticipate that they will engage in fact and expert discovery on issues of infringement and validity of the '720 patent.

If the parties anticipate that additional time beyond that allowed by the assigned discovery track will be needed to complete discovery or that discovery should be conducted in phases or be limited to or focused upon particular issues, please state those reasons in detail below:

The parties propose modification to the deadline for submission of infringement contentions under Patent L.R. 4.1, in order to allow Plaintiffs time to review the Osmotica ANDA and related documentation concerning technical details of the Osmotica ANDA Product. The parties propose a seventy-five (75) day period of review beginning on the date Plaintiffs received the Osmotica ANDA (May 9, 2012), making the deadline for infringement contentions July 23, 2012. Such an extension will allow for, *inter alia*, entry of a stipulated confidentiality order.

The parties additionally propose a two-month extension to the eight-month discovery track typically assigned to patent cases. The parties anticipate that such

extension is necessary in light of, *inter alia*, the need for discovery outside the borders of the United States. Four of the parties, Cosmo Technologies Limited, Giuliani International Limited, Osmotica Kft, and Osmotica Argentina are foreign entities. Additionally, all four inventors of the '720 patent reside in and are citizens of Italy; documents relating to, *inter alia*, conception and reduction to practice and manufacture of Lialda[®] are located in Italy. Depositions of individuals and production of documents associated with at least these foreign entities and activities will likely require travel and the use of translation services, both of which will consume time and resources.

As a final matter, the parties propose modification of the schedule such that expert discovery concludes prior to briefing on issues of summary judgment. The parties believe that such modification is logical and necessary, in light of the parties' anticipated use of expert witnesses on issues of infringement and validity of the '720 patent.

In view of the above and without waiver of request to further modify the case schedule as future circumstances may warrant, the parties present the following proposed schedule¹:

¹ The parties' proposed schedule provides for slight extensions of certain deadlines, given the intervening holidays.

Event	Local Rule Deadline	Agreed Proposed Deadline
Start of Discovery	5/24/2012 (30 days after Answer)	5/24/2012 (30 days after Answer)
Joint Preliminary Report and Discovery Plan (“JPRDP”) Due	5/24/2012 (30 days after Answer)	5/24/2012 (30 days after Answer)
LPR 4.1 Infringement Contentions (“4.1 IC”)	6/25/2012 (30 days after JPRDP)	7/23/2012 (75 days after receipt of ANDA)
LPR 4.2 Response to Infringement Contentions	7/25/2012 (30 days after 4.1 IC)	8/22/2012 (30 days after 4.1 IC)
LPR 4.3 Invalidity Contentions (“4.3 IC”)	7/25/2012 (30 days after 4.1 IC)	8/22/2012 (30 days after 4.1 IC)
Exchange of Proposed Terms for Claim Construction	8/22/2012 (90 days after JPRDP)	10/22/2012 (60 days after 4.1 IC and 4.3 IC exchange complete)
Exchange of Preliminary Constructions	9/11/2012 (20 days after exchange of terms)	11/12/2012 (20 days after exchange of terms)
Joint Claim Construction Statement (“JCCS”)	10/1/2012 (130 days after JPRDP)	12/3/2012 (20 days after exchange of preliminary constructions)
Complete Discovery for Claim Construction	10/16/2012 (15 days after JCCS)	12/21/2012 (20 days after JCCS)
Opening Claim Construction Briefs	10/31/2012 (30 days after JCCS)	1/18/2013 (30 days after JCCS)
Responsive Claim Construction Briefs	11/20/2012 (20 days after opening brief)	2/7/2013 (20 days after opening brief)
Claim Construction Hearing	December 2012	February 2013
Close of Fact Discovery*	1/22/2013	3/22/2013

Event	Local Rule Deadline	Agreed Proposed Deadline
(45 days after claim construction order if time is < 30 days)	(8 months after start of fact discovery)	(10 months after start of fact discovery)
Settlement Conference	2/5/2013 (14 days after close of discovery)	4/5/2013 (14 days after close of discovery)
Motions for Summary Judgment	2/21/2013 (30 days after close of discovery)	30 days after close of expert discovery
Consolidated Pretrial Order and <i>Daubert</i> Motions Due	2/21/2013 (30 days after later of either: close of discovery, or ruling on motions for summary judgment)	30 days after close of expert discovery or rulings on motions for summary judgment
Opening Expert Reports	2/21/2013 (30 days after close of discovery)	30 days after claim construction order
Responsive Expert Reports	3/25/2013 (30 days after opening expert reports)	30 days after opening expert reports
Reply Expert Reports	4/4/2013 10 days after responsive expert reports	20 days after responsive expert reports
Close of Expert Discovery	5/13/2013 (within 37 days of reply expert reports)	45 days after responsive expert reports

11. Discovery Limitation and Discovery of Electronically Stored Information:

(k) What changes should be made in the limitations on discovery imposed under the Federal Rules of Civil Procedure or Local Rules of this Court, and what other limitations should be imposed?

The limit imposed by Fed. R. Civ. P. 30(a)(2)(A)(i) of ten (10) depositions shall be exclusive of expert depositions. Depositions shall be limited to seven (7) hours per deponent. Every seven (7) hours of testimony given pursuant to a Rule 30(b)(6) notice will be counted as one deposition regardless of the number of witnesses designated or topics covered. If a foreign language interpreter is required for a deposition, two-thirds the time of the deposition shall be counted toward deposition time limits. Time shall be measured by the actual time the deponent is testifying during examination by counsel for each party, exclusive of recesses and off-the record conversations. The parties reserve the right to agree to additional depositions or to move the Court for additional depositions.

The limit imposed by Fed. R. Civ. P. 33(a)(1) of twenty-five (25) interrogatories including all discrete subparts shall be sufficient, without prejudice to either party's right to move the Court for interrogatories in excess of such limit. Requests for admissions shall be limited to seventy-five (75) per side, exclusive of those directed to authenticity of documents, which shall be unlimited in number.

(1) Is any party seeking discovery of electronically stored information?

 X Yes

 No

If “yes,”

(3) The parties have discussed the sources and scope of the production of electronically stored information and have agreed to limit the scope of production (e.g., accessibility, search terms, date limitations, or key witnesses) as follows:

The parties have agreed to discuss the source and scope of electronically stored information, including search terms, custodians, and time frames, at a later date and time.

(4) The parties have discussed the format for the production of electronically stored information (e.g., Tagged Image File Format (TIFF or .TIF files), Portable Document Format (PDF), or native), method of production (e.g., paper or disk), and the inclusion or exclusion and use of metadata, and have agreed as follows:

Requests for production of electronically stored information pursuant to Fed. R. Civ. P. 34 and 35 shall not include metadata absent an affirmative showing of good cause by the requesting party. Both parties are required to maintain metadata for each document produced. The requesting party shall bear all reasonable costs associated with the production of additional metadata.

Requests for production of electronically stored information pursuant to Fed. R. Civ. P. 34 and 35 shall not include production of native electronic files absent an

affirmative showing of good cause by the requesting party why it needs production of files in their native file format. Absent such a showing, all responsive files will be produced using the file format described below. The requesting party shall bear all reasonable costs associated with the production of files in native format.

All parties are prepared to engage in reasonable electronic discovery in response to discovery requests. Documents and electronically stored information shall be produced on a rolling basis in the following file format: Single-page .tiff (Group IV) images with (1) corresponding multi-page text files for each document; and (2) Defendants will provide Summation DII files and Plaintiffs will provide Concordance DAT files along with OPT/LOG files. The load files provided with the .tiff images shall contain the following data: BegDoc, EndDoc, attachment information (Defendants will provide BegAttach and EndAttach, and Plaintiffs will provide Parent ID and Attach ID), and PageCount. In responding to Email Production Requests, the load file shall also contain the following data (if available): SentDate (Format: MM/DD/YYYY), ReceivedDate (Format: MM/DD/YYYY), TimeSent, From, To, CC, and BCC.

Each production will be provided as single-page TIFF IV images with a resolution of not less than 300 DPI, with a Bates-like numbering stamp, and any necessary confidentiality legend/stamp. The Bates-like numbering stamp should

include a numeric prefix and zero-padded numbering. TIFF images should appear in a folder entitled “IMAGES.” Load files should appear in a folder entitled “DATA.” Text and/or OCR files should appear in a folder entitled “TEXT.” Along with the images, .dat and .opt format load files will be provided and the volume name included in the file path. The load file will include document breaks indicating the beginning and ending Bates numbers for each document. When document level OCR text files are provided, each OCR text file should bear the same name as the Production number of the first page of each document.

To the extent that a party possesses OCR files, such files will be included in the document production. However, no party shall bear an affirmative obligation to provide documents with OCR searchable text.

To the extent that a party possesses information related to the “source” of a document (*i.e.*, the name of the custodian, or, if not available, the storage location of the document), such information shall be provided when the documents are produced. However, no party shall bear an affirmative obligation to provide such “source” information for all produced documents. Further, such “source” information may be provided by (1) appearance in the “Source” and/or “Custodian” field for each document in the load file associated with the .tiff images or (2) by identification of documents from a particular “source” by Bates Numbers.

In the absence of agreement on issues regarding discovery of electronically stored information, the parties shall request a scheduling conference in paragraph 9 hereof.

12. Other Orders:

What other orders do the parties think that the Court should enter under Rule 26(c) or Rule 16(b) and (c)?

The parties are in the process of preparing and anticipate submitting a proposed Stipulated Protective Order pursuant to Fed. R. Civ. P. 26(c) and Local Patent Rule 2.2.

13. Settlement Potential:

(m) Lead counsel for the parties certify by their signatures below that they conducted a Rule 26(f) conference that was held on May 9, 2012, and that they participated in settlement discussions. Other persons who participated in the settlement discussions are listed according to party.

For Plaintiffs: Lead counsel (signature):

/s/ Edgar H. Haug
Edgar H. Haug
Frommer Lawrence & Haug LLP
745 Fifth Avenue
New York, NY 10151
(212) 588-0800

Other Participants:

David A. Rabin
Morris, Manning & Martin, LLP
1600 Atlanta Financial Center
3343 Peachtree Road, NE
Atlanta, GA 30326
(404) 233-7000

For Defendants: Lead counsel
(signature):

/s/ Robert F. Green
Robert F. Green
Leydig, Voit & Mayer, Ltd.
180 N. Stetson Ave., Suite 4900
Chicago, IL 60601

Other Participants:

Matthew Warezak
Smith, Gambrell & Russell, LLP
Promenade Two, Suite 3100
1230 Peachtree Street N.E.
Atlanta, GA 30309

(n) All parties were promptly informed of all offers of settlement and following discussion by all counsel, it appears that there is now:

<input type="checkbox"/>	A possibility of settlement before discovery.
<input checked="" type="checkbox"/>	A possibility of settlement after discovery.
<input type="checkbox"/>	A possibility of settlement, but a conference with the judge is needed.
<input type="checkbox"/>	No possibility of settlement.

(o) Counsel (☒) do or (☐) do not intend to hold additional settlement conferences among themselves prior to the close of discovery. The proposed date of the next settlement conference is _____, 20__.

(p) The following specific problems have created a hindrance to settlement of this case:

Unknown at present.

14. Trial by Magistrate Judge:

Note: Trial before a Magistrate Judge will be by jury trial if a party is otherwise entitled to a jury trial.

(q) The parties (____) do consent to having this case tried before a magistrate judge of this Court. A completed Consent to Jurisdiction by a United States Magistrate Judge form has been submitted to the clerk of court this ____ day of _____, of 20__.

(r) The parties (X) do not consent to having this case tried before a magistrate judge of this Court.

/s/ Edgar H. Haug
Counsel for Plaintiffs

/s/ Robert F. Green
Counsel for Defendant

SCHEDULING ORDER

Upon review of the information contained in the Amended Joint Preliminary Report and Discovery Plan form completed and filed by the parties, the Court orders that the time limits for adding parties, amending the pleadings, filing motions, completing discovery, and discussing settlement are as set out in the Federal Rules of Civil Procedure and the Local Rules of this Court, except as herein modified:

The schedule as adopted by the Court shall govern this case.

IT IS SO ORDERED, this ____ day of _____, 20__.

The Honorable Amy Totenberg
United States District Judge